Clinical challenges

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The generation of an idea, the investigation of a concept and the defence of a thesis is part of academic life. *Arthur Schopenhauer,* the 19th Century German philosopher, suggested that any great idea goes through three distinct phases: ridicule, opposition and finally enthusiastic acceptance. While an idea might not be categorized into such distinct divisions, progress in any field depends on the enthusiasm and focus of individuals who are willing to see this process through.

If we accept the well known quotation of Mahatma Gandhi who said: “whatever you do will be insignificant, but it is very important that you do it”. It perhaps makes us realise that many of our contributions, although small, are part of a continuum that moves a subject to extinction or maturity, as the case may be.

The principles of medical challenges are maybe somewhat different, because they must be tempered with ethical considerations, compassion and ensuring no harm. Teamwork and a long term focus on the issues are not possible without adequate finance and many areas of research are now carried out by large pharmaceutical and manufacturing companies, which have an eye on marketability of the end product.

This poses new ethical challenges, so process controls, audit and accountability become important issues for the profession. Let me take for an example a large hospital that saw itself as successful with a busy hip replacement programme in the early days of this type of surgery and before the medical devices standards were established. Some patients had problems with infections, but they could be controlled, and some hip prostheses failed. That was seen as the routine – but then a surgeon from another hospital not far away, which used the same devices, came to visit, he was very surprised to find the high rate of complications, which he had never encountered. It was only then when the process of surgical care was compared, did the first hospital realise that, not only was their technique different, but the metal hip prostheses were not adequately sterilised before insertion. The past 18 months had been spent carrying out a procedure without questioning the technique, the suitability of the device to be implanted, or comparing the results with others. This is one example of how an inter-centre comparison works.

Take the care of a child with a cleft of the lip and palate, which requires long term care from a multi-disciplinary team. It took the European multi-centre study, called EuroCleft, which compared outcome success amongst international centres against an agreed gold standard, to highlight the enormous differences in the type of surgery carried out, the experience of the surgeon and the standard of the end result. As a result of findings of this study the United Kingdom Health Department took the unusual step of reducing from 57 centres carrying out lip and palate surgery to around 12, and so created a few multidisciplinary centres of excellence for cleft lip and palate care, defining who should do the surgery, the minimum number of

procedures a year to maintain proficiency, the timing of interceptions and the appropriate audit routines.

These activities are all part of delivering quality to Clinical Care, which should involve both practitioner centred and patient centred evaluations, together with maintenance of standards through process evaluations and inter- and intra-centre audits of outcome.

Government health departments and insurance agencies have considerable interest in quality issues regarding the delivery of a clinical service, value for money and evidence based practice. In the United Kingdom the department of health has set up a National Institute for Clinical Excellence. This organisation is concerned with standards of care and patient satisfaction, internal and external audit of the outcomes of treatment, and the development of consensus over the clinical management process of a wide range of medical and surgical procedures.

Medical and dental education is becoming a process of life long learning, guided and focussed towards specialisation in a relatively narrow area of clinical activity. This poses a dilemma and represents our first challenge; one hears that the educational process should be modified, and learning channelled towards a particular field of interest.

In dentistry, at least in one school, the students can select a specialist profile which can exclude parts of the established curriculum. As a logical extension of these activities, the newly qualified medical or dental practitioner is becoming different to

traditional expectations that the public has. The all embracing doctor does not exist anymore, there is no possibility that a new graduate would be competent to administer anaesthesia, deliver babies, and carry out an appendectomy, yet this was taught to a proficiency level, although at a basic level, in many medical curricula in the past.

This is the age of increased specialisation, but with it has come the development of greater responsibility for nursing and para-medical personnel. A new job title has had to be created to describe the increased responsibilities that have been shouldered by hospital workers. The title of ‘professions complimentary to medicine and dentistry’ has evolved and training and registration authorities have had to recognise and regulate the activities of this new group of practitioners.

The question has been asked: “Does this improve the quality and standard of care?” The answer may lie in the audit results. The success of a knee or hip replacement procedure can be measured against mobility improvement and pain reduction and a specialist in this field who does nothing but this type of surgery may score highly in terms of outcome success.

The problem is: who manages the patient, the general physical status and the impact the specialist work has on other aspects of well-being. It seems that this responsibility is often devolved to junior staff in training and the professions complementary to medicine. The challenge is to ensure that with increasing specialisation, we don’t overlook the individual in our attempt to focus on the problem.

In a world of finite resources there have to be priorities, specialist care is quite often expensive, and in a public health care system this can place a strain on the health budget.

One particular problem is the very high costs of pharmaceutical products, and a recent newspaper headline describes this dilemma, and the personal challenge to a patient seeking expensive treatment, when this involved having to sell the family home to meet the hospital charges for medication.

So how well do we focus on the patient, or are we more concerned with the procedure? Do we respect autonomy and the rights of the patient; do we have a patient's charter and do we have in place all the checks and balances that are patient-centred, so evaluations can be made that involve patient satisfaction? Surely this is a most important area for the patient, who wants as much information as possible, to help make a decision on treatment proposals.

There are of course 'grey areas' and many are cost-related – but newspaper headlines are very ready to accuse the profession when communication breaks down. Another headline appeared recently which proclaimed: "Our father was sitting up in bed but now doctors want to kill him". It transpired that he was 86, required dialysis but was lucid and could eat and drink satisfactorily. Somehow the family had formed the impression that the hospital wanted to get rid of old people because they were too expensive. How bad the communication must have been between the patient, family and hospital to ever allow the family to contact the press to get their voice heard.

The clinical challenge posed by the principles of ethics, compassion and do no harm had all broken down here.

I propose to structure this presentation around 4 challenges that health care workers have to shoulder.

1. The challenge of quality, audit, and maintaining standards.
2. The challenge of cost effectiveness, adequate manpower and resources.
3. The challenge of ‘do no harm’ and maintenance of equality of care.
4. The challenge of progress.

The Challenge of Quality, Audit and Maintaining Standards

Perhaps the most important of these 4 areas is the overall maintenance of quality in clinical care, and this implies patient or customer satisfaction. The clinician who proclaims ‘he has always done it this way, and it seems to work’ has no longer any firm foundation on which to base this continued approach.

Without comparison with the outcomes from other clinicians and other centres, the clinician might have been doing it wrong for a whole career, or maybe was doing it better than everyone else. Somehow we need to measure treatment change and evaluate outcome, not only in terms of technical success, but also in the improvement in quality of life and the cost-effective nature of the overall care. Then we need to compare our results with other centres doing the same procedures. Then we need to change as a response to identified problems, and in this way aim to have a cycle of continuous improvement built into our processes.

I feel quite pleased to be able to say that in orthodontics we have developed indices of need and complexity, and have had evaluators of outcome for many years. These were developed by Shaw and Richmond and have been further refined to reflect patient aesthetic need and satisfaction. In 1993 the European Commissioners in Brussels awarded a grant to a group of orthodontic researchers, of which I was one of their number based in Amsterdam, to create a framework for delivering quality by orthodontic professionals. This was called EUROQUAL and this initiative was chaired by Professor Birte Prahl-Andersen and this had a wide impact on the delivery of orthodontic care. The study for the first time obtained a broad consensus over the indicators for treatment, the treatment process and the outcome evaluation. In effect, using the industrial concept of total quality management (TQM) used by manufactures to ensure consistency of outcome and customer satisfaction.

If the profession does not immediately have a focus on quality, then the medical defence companies certainly do. They must manage risk, because they take on the liability when things go wrong. There are medical institutions and organisations in many places in the world that have agreed a consensus of approach to management and treatment of each medical and surgical problem that the specialist encounters. This exerts control over the clinician, but it prevents a ‘wild card’ approach being used when its efficacy is not proven. The clinician then has to accept that the work must be done to established guidelines, using evidence based protocols. This consensus approach will certainly become much more relevant in the future. Claims for negligence are on the increase and settlements are getting larger. Some clinical areas in the Unites States of America, such as obstetrics and gynaecology, have

such high medical indemnity fees that recruitment and maintaining specialist practitioners in these ‘high risk’ specialities is becoming difficult.

Consensus is now building for this evidence-based approach in health care to be followed, and this has a considerable champion in the Cochrane Collaboration, which is a non-profit making organisation concerned with providing up-to-date information with evidence-based data bases using systematic reviews of the results of randomised controlled trials.

The Cochrane collaboration is named to honour Archie Cochrane a British medical researcher. Before he qualified in medicine in 1936 he was a research student in Strangeways Laboratory in Cambridge working on tissue culture studies. During the war he was a captured and incarcerated in a prison camp in Crete and subsequently became the prison doctor, where he certainly had to live in a world of ‘finite resources’, a comment he frequently alluded to. He describes how he treated 20,000 prisoners of war as the only doctor and with only a ramshackle hospital, some aspirin, antacid and some skin antiseptic. He is perhaps best known for his classic text – Effectiveness and Efficiency – Random Reflections on Health Service published in 1972 where he makes the point that - doing the right thing is being effective and doing things right is being efficient.

Many variables come into providing quality care for the patient, and we have to be certain that what we do, occasions no harm, and is based on the evidence that it will work, and in these days of finite resources it is cost effective.

It is well worth while for me to quote an example of appropriate care from Cochrane's autobiography – One Mans Medicine – published the year after he died in 1989. I quote 'Another event at the prison camp had a marked effect on me. A young Soviet prisoner was dumped in my ward late one night. The ward was full, so I put him in my room as he was moribund and screaming and I did not want to wake the ward. I examined him. He had obvious gross bilateral cavitations and a severe pleural rub. I thought the latter was the cause of the pain and screaming. I had no morphia, just aspirin, which had no effect. I felt desperate. I knew very little Russian then, and there was no-one in the ward who did. I finally instinctively took him in my arms, and the screaming stopped almost at once. He died peacefully in my arms a few hours later. It was not the pleurisy that caused the screaming but loneliness. It was a wonderful education about the care of the dying. I was ashamed of my mis-diagnosis and kept my story secret.'

How much better a clinician we would all be if we had access to all the information and resources we needed to approach each diagnostic problem we encountered in the most effective and efficient way, but like Cochrane we all must be humble enough to say 'I got it wrong'.

The World Health Organisation has a regional office for Europe based in Copenhagen with a focus on quality of care. The cost-effective nature of management of paediatric diabetes was studied in Europe some years ago using best practice at that time, and outcome assessments made on blood sugar control, adjusted costs, manpower and number and frequency of hospital visits. Copenhagen was acknowledged at that time as being in the forefront of the management of this

condition – it was therefore quite surprising that the city hospital in Bucharest in Romania came out best in that study. In effect you could control this condition using evidence based procedures, at the least cost, and with the least number of hospital visits, and with the least manpower requirement, in what was a then at that time a developing economy.

It serves to demonstrate, that given the right information from the right data bases, effective and efficient and cost effective management of human disease can be achieved. Maybe not without good cause the last meeting of the WHO Regional Meeting for Europe was in Bucharest in September this year.

The Challenge of Cost Effectiveness, Adequate Manpower and Resources.

Cost effectiveness will always be a problem for providers when, for the costs of one multi-transplant procedure, a developing nation could build a plant to produce clean drinking water for a town. One however sees this aspect of care, involving transplants, being more common, but as costs are contained more economies of scale are possible, and more certain outcomes can be anticipated. It is therefore important to be able to take a balanced view of these issues, and in treatment centres, priorities can be established that make for this balanced approach to health care service for each discipline, with their separate budgetary requirements. There will always however be high cost disciplines, and the implementation of audit and cost control measures here are so important to ensure value for money and cost effectiveness. This ensures that the procedures being carried out are offered to those who stand to benefit most, and in whom the outcomes are more likely to result in success.

We read in the press how difficult is it for health care costs to be contained, and how much of a nations' budget needs to be committed in a socialised health structure to allow free access to care for all. Costs very easily spiral out of control, budgetary targets are not met, then access to care is denied, so costs have to be reduced, and that usually means less manpower – so overall the patient suffers.

Completely free access to a broad spectrum of care is no longer realistic, and contributions must come from patients, insurance companies and the state in shared partnerships.

The best investment is however prevention – smoking is so damaging to health and quality of life, both for the smoker and the world at large who inhale the by-product, that money spent on education about its dangers, particularly to young people, is well spent if it results in less long term incapacity in that population.

The maintenance of a healthy life-style certainly allows for pleasurable experiences because the evidenced based health advantages of red wine are well documented and even if we over-indulge then we can call on the positive advantages to our circulation of a couple of aspirin tablets.

How we share resources in a society, and how we educate our health providers, and how the system provides continuing employment are all closely inter-linked and resource dependent, but like any large conglomerate business, the health care industry needs to be well managed. At this level it is up to the professional managers

and politicians whose job it is to ensure the development of appropriate health care policies and strategies and educational resources to support the activities of the health sector.

The Challenge of 'Do no harm' and Maintenance of Equality of care

The recuperative power of the human body is considerable, and survival even in the most disadvantageous circumstances is possible. As progress is made in medical research and knowledge, new information, techniques and pharmaceutical agents are developed to extend further this power and create a situation where even severe chronic conditions can be controlled and the quality of life improved, where previously this would have resulted in death.

This poses difficulties because the challenge of 'do no harm' is partially delegated to large pharmaceutical companies where profit is an overriding consideration. We must rely on rigorous controls, animal testing of products and carefully structured clinical trails of new drugs before these are used. Even so there are real problems when a product is marketed aggressively. The prescriber has to reply on product information provided and be watchful of adverse reactions, and report these to drug control agencies. The enormous problem that Thalidomide caused is well known. In the 1960s it was used by pregnant women in Europe and Canada to treat morning sickness. Women who took the drug in early pregnancy gave birth to children with severe birth defects such as missing or shortened limbs. This resulted in the total withdrawal of this product worldwide, however recently it was discovered that it is effective in treating symptoms of leprosy and the Federal Food and Drug Administration (FDA) in the Unites States have now approved its use again under

strict guidelines. Further trails are ongoing as there also seem benefits in treating symptoms associated with AIDS, lupus, sjogren syndrome, rheumatoid arthritis, inflammatory bowel disease and macular degeneration.

One of the biggest problems to emerge recently has been due the heart and stroke induced effects of Vioxx the painkiller, recently withdrawn from the market place. In a legal case of negligence against the company involving the death of a man from cardiac arrhythmia, a Texas court awarded $253m damages against the pharmaceutical company. This implied corporate liability which does not involve individuals, but this case is different and the US Justice Department is now conducting a criminal investigation into the companies handling of Vioxx, which could result in convictions of former executives and employees. The sheer number of possible actions likely to be brought for negligence may indeed bankrupt the company.

When a medical practitioner is always open to risk of litigation for wrong doing, it seems only fair that corporate problems should identify a face or faces and not allow limited liability to hide those directly negligent, if that is able to be proven.

This brings me to another point which I mentioned earlier, namely the costs of new products which are expensive not only to cover the development costs but companies are now having to think forward to have liquidity to not only defend lawsuits , but also to be able to pay large claims to thousands of patients when things go wrong.

This has a big impact on the equality of care and this is has no better example than the AIDS epidemic in Africa. According to the United Nations Children's Fund (UNICEF), one out of every five people in Zambia is HIV-positive, and virtually everybody in the country is affected or infected by HIV or AIDS. Why, when antiretrovirals (ARV's) are so effective are they not available to all who would benefit.

The answer lies in the costs; and while generic production has brought the prices down for first-line retrovirals from US $10,000 in 2000 to as little as US $150 per patient per year in 2004, there are still immense problems, political and logistic, which prevent those who's need is greatest, obtaining the medication. So hundreds of thousands of people are dying for want of drugs they cannot afford.

The Challenge of Progress

Finally I mention the challenge of progress. We all like our comfort zone and we do like to change our routines or learn new things. Maybe –to use an anonymous quote– the only person who likes change is a wet baby.

There are 2 types of resistance to change and progress. One is organizational resistance to new ideas and activities and the other is personal resistance.
Both can have some positive effect to slow a process down so that there is time to reflect, form a consensus and develop a new approach, but they can so easily be used in a non-productive way to stifle innovation and creativity. In a health care context we want to be able to have a human response which shows compassion in areas of need when change exerts a real and tangible benefit to health and well-being.

I return to the EuroQual study, which I mentioned earlier, where I personally witnessed the difficulty of obtaining consensus over treatment approaches. Delegates were assembled at a congress centre at Noordwijkerhout representing the profession from each EC member state. Some delegates listened and reflected, some contributed opinions, some were ready to accept that what they did, needed to be re-thought, but some groups just withdrew and did not vote because they did not agree that their autonomy or any of their colleagues' clinical judgements should be affected and maybe ultimately controlled my any consensus opinion.

The majority opinion ultimately prevailed, but having reached a conclusion this did not mean change was imminent, because the implementation phase, which came next was perhaps the most difficult.

I use this example just to say – be careful of just saying no – be responsive to new ideas, - allow new initiatives space and support to develop, and like Archie Cochrane have the courage to say "I got it wrong".

To close

Rector, ladies and gentlemen – the information I have presented is based on personal experiences as an educator, clinician and researcher. We cannot fail to be aware that during our careers we see changes and new perspectives, and have to be responsive to new ideas. What I have discussed I hope is 'food for thought' and will stimulate the minds of all of us here who are involved in patient care.

Words of thanks

As this is the end of my oration I would like to express my thanks to the Rector Magnificus, the Board of Governors of the Rijksuniversiteit Groningen, Professor Sibrand Poppema, Dean of the Medical Faculty in the University Medical Center Groningen, and Professor Lambert de Bont, Head of the Department of Oral and Maxillofacial Surgery, and Professor Warner Kalk, chairman of the discipline of dentistry. Your support and confidence in me has been much appreciated.

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The final word is saved for my family and close friends, thank you for being with me, for your understanding and unfailing faith in my ambitions. John Donne the 17 century preacher and Dean of St Paul's Cathedral in London, and famous for his sermons and meditations – in one he says "All mankind is of one author, and is one volume - and no man is an island, entire of himself".

Ik heb gezegd.